UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,452	11/27/2001	Nissim Benvenisty	1822/117	2188

2101 7590 04/02/2003

BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	10

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,452	BENVENISTY ET AL.	
	Examiner	Art Unit	
	Thai-An N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to methods of altering gene expression in a population of human embryonic stem cells, classified in class 435, subclass 455+, for example.

II. Claims 18-23, drawn to methods of purifying pluripotent embryonic stem cells, classified in class 435, subclass 4.

III. Claims 24-35, drawn to methods of treating a human subject by introduction of transfected human embryonic stem cells, classified in class 424, subclass 93.21.

IV. Claims 37-42, drawn to methods of producing clonal pluripotent cell populations from a mixture of pluripotent and differentiated cells, classified in class 435, subclass 4.

V. Claims 43 and 44, drawn to methods of regulating cell viability of a population of cells in a subject, classified in class 424, subclass 93.21.

VI. Claims 45-47, drawn to methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro*, classified in class 435, subclass 4.

VII. Claims 36, 48-56, drawn to cell population and reagent cell populations which consists of genetically modified pluripotent human embryonic cells, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Invention I and any one of Inventions II-VI are mutually exclusive and independent methods. The method of altering gene expression in a population of human embryonic stem cells of Invention I is not required for the implementation of

the methods of purifying pluripotent embryonic stem cells of Invention II, the methods of treating a human subject by introduction of transfected human embryonic stem cells of Invention III, the methods of producing clonal pluripotent cell populations from a mixture of pluripotent and differentiated cells of Invention IV, the methods of regulating cell viability of a population of cells in a subject of Invention V and the methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the genetically modified pluripotent human embryonic stem cells can be made by calcium chloride transfection.

Inventions II and any one of Inventions III-VII are mutually exclusive and independent inventions. The methods of purifying pluripotent embryonic stem cells of Invention II are not required for the implementation of the methods of treating a human subject by introduction of transfected human embryonic stem cells of Invention III, the methods of producing clonal pluripotent cell populations from a mixture of pluripotent and differentiated cells of Invention IV, the methods of

regulating cell viability of a population of cells in a subject of Invention V, the methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI, and the genetically modified cell populations of Invention VII, and vice versa.

Invention III and any one of Inventions IV-VII are mutually exclusive and independent. The methods of treating a human subject by introduction of transfected human embryonic stem cells of Invention III are not required for the implementation of the methods of producing clonal pluripotent cell populations from a mixture of pluripotent and differentiated cells of Invention IV, the methods of regulating cell viability of a population of cells in a subject of Invention V, the methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI, and the genetically modified cell populations of Invention VII, and vice versa.

Invention IV and any one of Inventions V-VII are mutually exclusive and independent. The methods of producing clonal pluripotent cell populations from a mixture of pluripotent and differentiated cells of Invention IV are not required for the implementation of the methods of regulating cell viability of a population of cells in a subject of Invention V, the methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI, and the genetically modified cell populations of Invention VII, and vice versa.

Invention V and either of Inventions VI or VII are mutually exclusive and independent. The methods of regulating cell viability of a population of cells in a subject of Invention V are not required for the methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI, and the genetically modified cell populations of Invention VII, and vice versa.

Invention VI and VII are mutually exclusive and independent. The methods for screening an agent to determine an effect on differentiation of pluripotent cells *in vitro* of Invention VI is not required for the genetically modified cell populations of Invention VII, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT
Thái-An N. Ton
Patent Examiner
Group 1632

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630